

Research Ethics Board
Office of Research Administration
Telephone: (416) 864-6060 Ext. 2557
Facsimile: (416) 864-6043
E-mail: pateld@smh.toronto.on.ca

April 27, 2006

Dr. Frances Silverman,
Gage Occupational and Environmental Health Unit,
St Michael's Hospital



Leading with Innovation
Serving with Compassion

ST. MICHAEL'S HOSPITAL

A teaching hospital affiliated with the University of Toronto

Dear Dr. Silverman,

Re: REB# 05-143 – Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures

REB APPROVAL:

Original Approval Date

April 27, 2006

Annual Review Date

April 27, 2007

At the St Michael's Hospital Research Ethics Board (REB) meeting held on July 27, 2005, the above referenced study was discussed and subsequently the views derived from this discussion have been documented and resolved.

The REB approves the study as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act, 2004. The REB hereby issues approval for the above named study for a period of 12 months from the date of this letter. Continuation beyond that date will require further review of REB approval. In addition, the following have been reviewed and are hereby approved:

1. The SMH consent form dated March 30, 2006;
2. The study poster advertisement dated April 05, 2006;
3. PM Center Study Newspaper Advertisement
4. The study protocol for project 3.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the Research Ethics Board.

This letter serves as approval by the SMH REB for conduct of this study; however, additional approvals are required as outlined on the Research Administration Authorization Check List form. Enclosed is a copy of this check list and REB authorization is in the appropriate space. Also, the Clinical Trial Agreements have to be submitted to the Research Office for review and approval. The remainder of the approvals **must be** coordinated through the Research Office prior to initiation of this research. All drug dispensing must be coordinated through the Research Pharmacy at 416-864-5413.

The SMH REB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada's Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials). Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

With best wishes,

Dr. Julie Spence
Chair, Research Ethics Board
JS/ks

Dr. Frances Silverman
05-143 - Approval Letter (Full Board Review) - 27-Apr-2006

30 Bond Street
Toronto, Ontario
M5B 1W8
416-360-4000

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7. Do you want the HSC to conduct a review of this project even if it is deemed exempt under federal regulations? If so, explain why (e.g., study involves particularly controversial issues, you want IRB feedback, etc.).

No

PI Signature

Date

For HSC Office Use Only: ☐ Exempt ☐ Non-exempt

☐ Exempt but HSC will review, because:

☐ Does not meet the definition of "research" 45 CFR 46.102(d)

☐ Does not meet the definition of "human subjects" 45 CFR 46.102(f)

☐ 45 CFR 46.101(b) _____ **REMEMBER: the (b)s do not apply to Prisoners, Pregnant Women/Fetuses/Neonates. Also: (b)(2) has very limited applicability to children.**
Best double-check!

☐ Training grant 45 CFR 46.118

☐ Program center or project grant 45 CFR 46.118

☐ Do Letter: "Specifically..."

☐ Do DHHS Cert

Reviewer: _____

Date: _____

Revised June 2004